DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 20, 2015

DaeSung Maref Co., Ltd.
c/o Mr. Dave Kim
8310 Buffalo Speedway
Houston, TX 77025

Re: K150033
Trade Name: LF-400 Compressible Limb Therapy System
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: March 20, 2015
Received: March 23, 2015

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150033

Device Name
LF-400 Compressible Limb Therapy System

Indications for Use *(Describe)*

LF-400 is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as : Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: March 20, 2015

I. SUBMITTER

Submitter's Name : DaeSung Maref Co., Ltd.
Submitter's Address: 298-24, Gongdan-Ro, Gunpo-shi, Gyeonggi-Do, Republic of Korea, 435-862
Submitter's Telephone: +82-31-459-7200
Contact person: Jae-Wha Lee / President

Official Correspondent: Dave Kim **(**davekim@mtech-inc.net**)**
(U.S. Designated agent)
Address: 8310 Buffalo Speedway, Houston, TX 77025
Telephone: +713-467-2607
Fax: +713-583-8988

II. DEVICE

Trade/proprietary name: LF-400 Compressible Limb Therapy System

Common or Usual Name: Air Compressible Limb Therapy System

Regulation Name : Powered Inflatable Tube Massager

Classification: 21 CFR 890.5650 (Product Code: IRP)

Regulatory Class: II

III. PREDICATE DEVICE

1) Primary Manufacturer : DaeSung Maref Co., Ltd.
   Device : LX7 (V7)
   510(k) Number : K102320 (Decision Date – Mar. 4, 2011)

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

LF400 is the pressurization system helping to relieve the symptom of lymphedema and prevent aggravation of symptoms by applying the air pressure to limbs.
LF400 comprises 4-step sleeves which move the body fluids through the limbs by evenly applying pressure to the limbs.

- Device Specification:

NO	Items	Specification
1	Model	LF400
2	Rating Protection Type	Class II, BF-Type Device
3	Usable Place	Indoor
4	Rated Voltage	100 - 127VAC, 50/60Hz
5	Power Consumption	50VA
6	Rated Fuse	3.15A/250V
7	Setting Pressure	Min. Max Pressure Range:20~140mmHg (unit:5mmHg) Manufacturer Recommended Pressure Range: 60~120mmHg
8	Setting Time	5~180 Minutes (unit:5 Min.)
9	Mode	A, B, C, Pre Therapy
10	Dimension	225(W) * 225(D) * 135(H)mm
11	weight	3.5Kg(main system only)

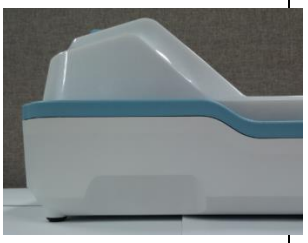
➢ Device Identification:

(1) Main Body

Front

Right

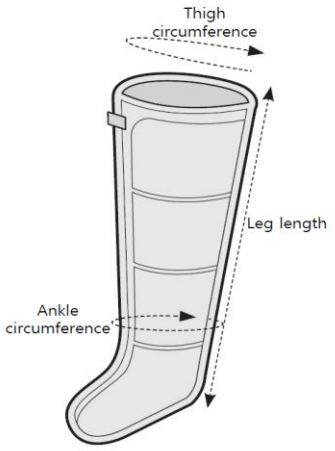
Left



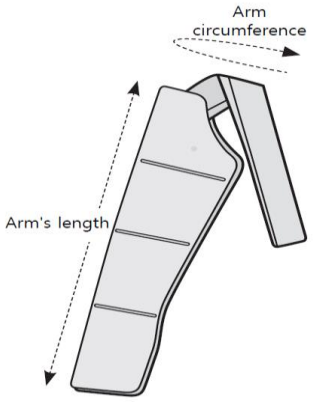
Top

Back

(2) Garment(Cuff)

Cuff	LEG Cuff
Image	 

<table>
<tr><td>Chamber</td><td>4 chamber</td></tr>
<tr><td>Pressure</td><td>Min. Max Pressure Range:20~140mmHg (unit:5mmHg)
Manufacturer Recommended Pressure Range: 60~120mmHg</td></tr>
<tr><td>Mode</td><td>A, B, C, Pre-therapy</td></tr>
<tr><td>Cuff Material</td><td>Nylon</td></tr>
<tr><td>Size</td><td>
<table>
<tr><th></th><th>Thigh circumference</th><th>Ankle circumference</th><th>Leg length</th></tr>
<tr><td>M</td><td>50cm</td><td>36cm</td><td>67cm</td></tr>
<tr><td>L</td><td>62cm</td><td>37cm</td><td>74cm</td></tr>
<tr><td>XL</td><td>74cm</td><td>43cm</td><td>79cm</td></tr>
<tr><td>XXL</td><td>79cm</td><td>46cm</td><td>92cm</td></tr>
</table>
※Tolerance : ± 2cm
</td></tr>
<tr><td>Biocompatibility test</td><td>ISO10993-5 (Cytotoxicity test)
ISO 10993-10 (LLNA:BrdU-ELISA)
ISO 10993-10 (Animal Skin Irritation test)</td></tr>
</table>

<table>
<tr><td></td><td>ARM Cuff</td></tr>
<tr><td>Image</td><td> 

</td></tr>
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<tr><td>Mode</td><td>A, B, C, Pre-therapy</td></tr>
<tr><td>Cuff Material</td><td>Nylon</td></tr>
<tr><td>Size</td><td><table><tr><td></td><td>Arm circumference</td><td>Arm's length</td></tr><tr><td>Arm Cuff</td><td>50cm</td><td>88cm</td></tr></table>※Tolerance : ± 2cm</td></tr>
<tr><td>Biocompatibility test</td><td>ISO10993-5 (Cytotoxicity test)
ISO 10993-10 (LLNA:BrdU-ELISA)
ISO 10993-10 (Animal Skin Irritation test)</td></tr>
<tr><td>Hose Image</td><td>  </td></tr>
<tr><td>Hose Length</td><td>256 CM</td></tr>
<tr><td>Hose Material</td><td>PVC</td></tr>
</table>

➢ Device Characteristics

(1) Components

The basic set of Air Compression Therapy System consists of the main body, which includes the air pump that generates air pressure and control panel, air hose that transfers air pressure and cutoff sleeve (cuff) for leg and its accessories include overlapping sleeve (cuff) for leg, cutoff sleeve (cuff) for arm, overlapping sleeve (cuff) for arm, cutoff sleeve (cuff) for waist and pants sleeve (cuff).

(2) Characteristics of the device

① Operation

The device consists of 4 parts-PCB, control panel, air pump (AC motor pump) and distributor (solenoid).

PCB consists of user input switch, LED or LCD display and button for pressure control and controls the air pump and solenoid via micro controller.
Air pump is connected to the hose and supplies air to the distributor.
Air distributor supplies the air to each air chamber in order and thus, repeats the inflation of Chamber 1 → inflation of Chamber 2 → inflation of Chamber 3 → inflation of Chamber 4 in this order until the end of the set time.

② Electric Characteristics

a. Rated Voltage: AC100-127V~

b. Rated Frequency: 50/60Hz

c. Power Consumption: 70VA

③ Protection against electric shock

Class Ⅱ, Type BF

④ Safety Measure

a. Fuse: 3.15A/250V

b. Air pump has a fuse on the circuit to protect against over temperature.

⑤ Software

a. File Name: LF400.c

b. Version: V1.0

c. Main features: switch, display, pump, solenoid, pressure control

V. **Indications For Use:**

LF-400 is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as : Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

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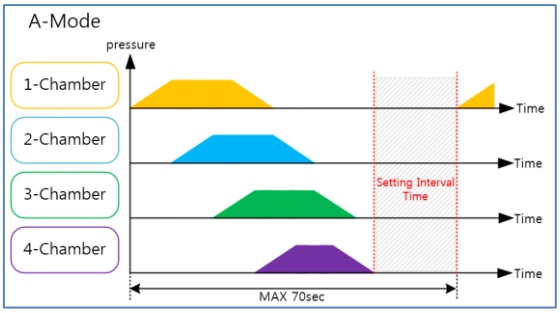
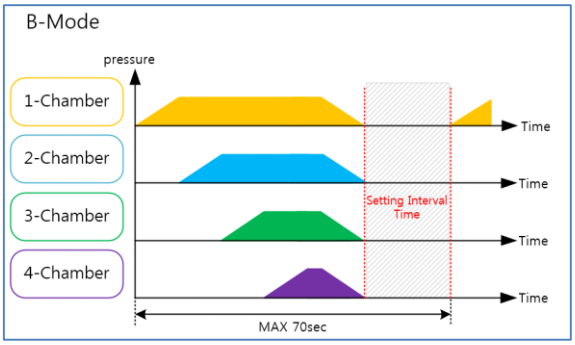
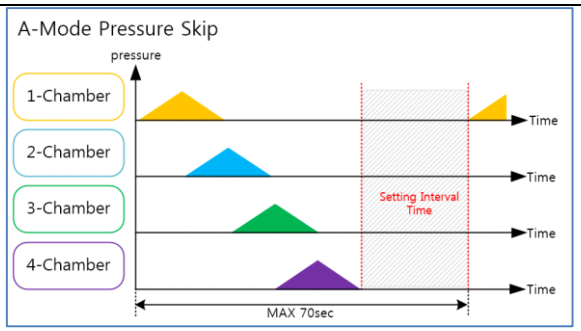
VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Model Name	LF400	LX7(V7)
510(k) Number	Not Assigned	K102320
Classification	Class II Device / IRP (21 CFR 890.5650)	Class II Device / IRP (21 CFR 890.5650)
Indications for Use	LF400 is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as : Primary lymphedema, Edema following trauma and sport injuries, Post immobilization edema, Venous insufficiencies, Lymphedema	LX7(V7) is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as Primary lymphedema, Edema following trauma and sport injuries, Post immobilization edema, Venous insufficiencies, Lymphedema.
Standard	EN ISO 14971 EN 60601-1 EN 60601-1-2	EN ISO 14971 EN 60601-1 EN 60601-2-10 EN 60601-1-2
Contraindications	Acute pulmonary edema Acute thrombophlebitis Acute congestive cardiac failure Acute infections Deep Vein Thrombosis (DVT) Episodes of Pulmonary embolism Wounds lesions or tumors at or in the vicinity of application Where increased venous and lymphatic return is undesirable Bone fractures or dislocations at or in the vicinity of application	Acute pulmonary edema Acute thrombophlebitis Acute congestive cardiac failure Acute infections Deep vein thrombosis (DVT) Episodes of pulmonary embolism Wounds, lesions, or tumors at or in the vicinity of application Where increased venous and lymphatic return is undesirable Bone fractures or dislocation at or in the vicinity of application.
Mode of Compression	Sequential	Sequential
Mode	3 modes (A,B,C) + Pre-therapy	3 modes

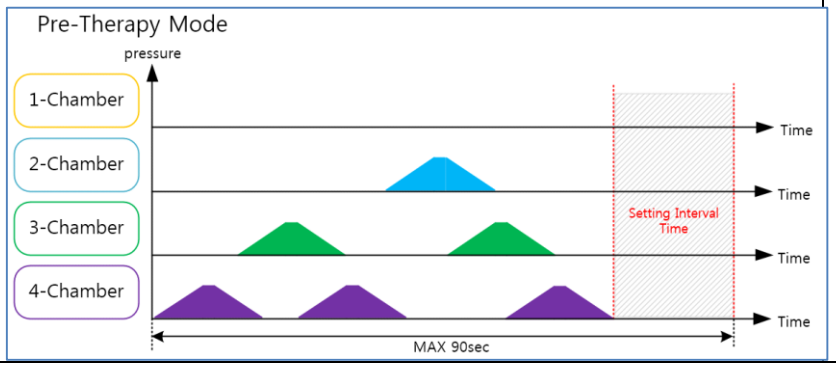
description	mode	
Power Source	For Pressure Therapy Units Electricity Supply:100-127V~,50/60Hz Electricity consumption:50VA	For Pressure Therapy Units Electricity Supply: 230 V~,50/60 Hz Electricity consumption: 50 VA
Therapy Time	5~180 minutes	10min, 20 min, 30min
Maximum and Minimum Pressure	Min. Max. Pressure range: 20~140mmHg Manufacturer recommended pressure range: 60 ~ 120mmHg	Min. Max. Pressure range : 0-230mmHg Manufacturer Recommended pressure range: 60~120mmHg
Number of Chamber	4 chamber	4 to 8 chamber
Compression Cycle Time	5~180 minutes	30min
Actual Picture		

Differences: Note 1. Description on Mode Difference

	Description	Verification Data	Risk Assessment
1	Pre-therapy Mode is the new mode. It's not for therapy but for reducing fatigue by finishing therapy continuously massaging from bottom(foot) to top(thigh) and massaging from top to bottom.	A-Mode Time Chart  B-Mode Time Chart  C-Mode Time Chart	Additional risks not concerns for safety and effectiveness (Refer to Risk Management Report)



Pre-therapy Mode
Time Chart



Differences: Note2. Description on Time Difference

	Description	Risk Assessment
1	The time setting for LX7, the predicate device, was in the unit of 10 min., 20 min., and 30 min. For additional treatment time, if necessary, the timer had to be reset by the user in every 10, 20 or 30 min. The time setting for LF-400, the new subject device, is available for 5 ~ 180minutes to provide the user more flexible control over the time setting, shorter or longer interval, than LX-7, the predicate device. A single treatment time setting of 5~180 minutes for LF-400 is within the usual treatment time range between 60 min ~ 960 minutes for treating Lymphedema patients, based on the prescription of a physician.	Additional risks not concerns for safety and effectiveness (Refer to Risk Management Report

Differences: Note3. Description on Pressure Difference

	Description	Risk Assessment
1	The pressure limit for LX7 ranges between 0~230mmHg and the manufacturer recommended pressure range was between 60~120mmHg (see page 13 of LX7 Manual). The air pressure setting for LF-400, the new subject device, ranges between 0 ~ 140mmHg and the recommended pressure range is identical to 60~120 mmHg to be aligned closely with the pressure setting found in usual Lymphedema treatment cases. In few Lumphedema treatment cases reported, the air pressure setting applied to treat Lymphedema patients ranged between 30~160mmHg based on the severity of the symptoms even though the same report indicated small number of patients experienced pain or discomfort at the pressure setting of 160mmHg.	The pressure range for LF-400 is smaller than the one for LX7. Additional risks not concerns for safety and effectiveness (Refer to Risk Management Report)

Differences: Note4. Description on Fabric Difference

	Description	Verification Data	Risk Assessment
1	LF-400, the new device, uses nylon for the cuffs, same material used for LX7(V7). OXFORD is the weaving method of fabric. It is not the element of fabric.	Dictionary definition on "OXFORD" Noun <Handicraft> Two or three threads are woven in parallel without being twisted.	The same fabric for cuffs is used for the subject and predicate device. Thus, Additional risks not concerns for safety and effectiveness (Refer to Risk Management Report)
2	OXFORD Composition Table shows that the device is made 100% with nylon.	OXFORD Composition Table 5407-41-0000 5110 N/210D SD 平 62" 100% NYLON F.YARN WOVEN FABRIC (OXFORD) IN GREY (SD) 62" (WOVEN BY SHUTTLELESS LOOM) WP : N.F.Y.210D/68 WT : N.F.Y.210D/54 TOTAL WEIGHT : 170GR/YD	

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility testing (ISO10993-5, ISO10993-10)
Electrical safety and performance testing were conducted according to standard IEC 60601-1: 2005 + CORR.1(2006) + CORR(2007) and EMC testing were conducted in accordance with standard IEC 60601-1-2:2007.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software would not directly result in serious injury or death to the patient or operator.

Overall Performance Conclusions

All test results were satisfactory.

VIII. CONCLUSIONS

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification DaeSung Maref Co, Ltd. concludes that LF-400 Compressible Limb Therapy System is safe and effective and substantially equivalent in comparison with LX7 (V7), the predicate device as described herein.